

**REMARKS/ARGUMENTS**

Reconsideration of the present application, as amended, is respectfully requested.

**A. STATUS OF THE CLAIMS**

As a result of the present amendment, claims 1-24 are again presented for continued prosecution. Claim 1 has been amended to insert on the last two lines that  $E_{2,4}$  are not simultaneously H. Thus, there are, at minimum, two equivalents of the linker on each polymer terminal. Support can be found throughout the specification see, for example any of the fully synthesized compounds in the figures such as 6a or 6b which shows two equivalents on the terminal. A similar change was made for claim 24. An obvious typographical error was addressed with claim 5.

**B. REJECTION UNDER 35 U.S.C. §103**

The Examiner has rejected the subject matter of claim 1-24 as being obvious in view of Greenwald et al. Reconsideration and removal of the rejection in view of the amendments made to the claims and comments made herein is respectfully requested. Greenwald et al. describe a specific trimethyl-lock (TML) based releasable polymer transport system. There is only a single TML linker portion linker attached to a terminal end of the polymer. Further, there is no disclosure or suggestion to modify the terminal of the PEG used by Greenwald to allow the higher degrees of loading afforded by the claimed invention. In contrast thereto, the present invention is directed to a higher-loading TML-based polymer transport system. As explained above and as a result of the amendment to claim 1, the terminally branched systems of the invention have at least two equivalents of the TML-based system on each terminal of the polymer. This can be further explained with a closer consideration of the claimed multi-functional moiety  $-NE_4-CE_{1,3}$  found at the terminal end(s) of the polymer. The presence of an aspartic acid-based terminal branching, for example, provides the artisan with a system capable

of higher degrees of loading for the therapeutic compounds of interest. The number of equivalents of linker with therapeutic agent or other D groups described herein on the termini of the polymer can be 2, 3, 4 or multiples thereof. Greenwald et al. teaches that only one equivalent of linker with drug can be attached to a terminal of the polymer. See Figure 1 of the Greenwald et al reference. Since there is no disclosure or suggestion in the reference that one could make such modifications and that it would be beneficial to do so in order to get higher degrees of loading, it cannot be said that the claimed invention would be rendered obvious by the reference. Reconsideration and removal of the rejection is therefore proper and respectfully requested.

**C. DOUBLE PATENTING REJECTION UNDER 35 USC 101**

In order to sustain a double patenting rejection under Section 101, it must be shown that the same invention has been claimed. Applicants wish to traverse the provisional rejection made by the Examiner in this case on the basis that this application and commonly assigned USSN 10/078,730 do not claim the same invention. As was pointed out in the response filed for the office action in the '730 application, the claims in that application were limited so that D<sub>1</sub> and D<sub>2</sub> are both not simultaneously OH. The overlap between the application has been removed. The Examiner makes mention of the variable "J" in the present application and the NR moiety in the '730 application. While it is true that both polymer transport systems include an amine as a part thereof, there is structural difference between the two claimed inventions as well as a result of the amendments made to the claims herein and in the '730 application.

Turning now to claim 18, Applicants respectfully direct the Examiner's attention to the fact that the potential groups for D in each application differ substantially. This application requires the D groups to include a trimethyl lock system moiety whereas the '730 application requires a benzyl elimination moiety. The US Patent Office has already acknowledged the uniqueness of the individual releasable systems. See commonly-assigned US Patent Nos.

5,965,119 and 6,180,095. Again, it is asserted that there is no identical subject matter being claimed. It is urged that the rejection be removed. In the event that the Examiner wishes to amend the rejection to an obviousness type double-patenting rejection, it is requested that the Examiner contact the undersigned by telephone so that the issue can be resolved without undue delay.

**D. PROVISIONAL EXTENSION OF TIME PETITION**

This response is being filed within the shortened period for response. Thus, no further fees are believed to be required. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

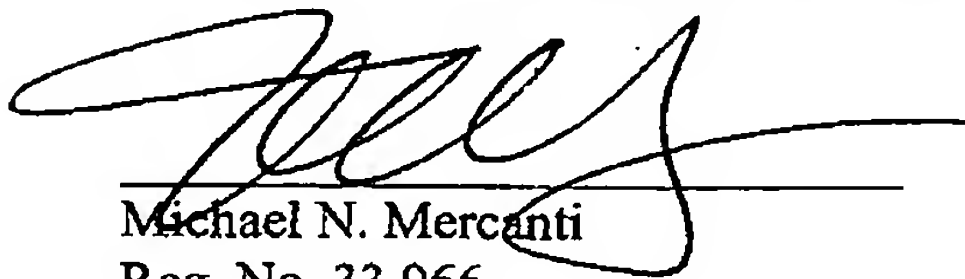
**E. CONCLUSION**

In view of the actions taken and arguments presented, it is respectfully submitted that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

MUSERLIAN, LUCAS & MERCANTI, LLP



Michael N. Mercanti  
Reg. No. 33,966

MUSERLIAN, LUCAS & MERCANTI, L.L.P.  
475 Park Avenue South  
New York, New York 10016  
Phone: 212-661-8000  
Fax: 212-661-8002